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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,001	03/11/2004	Hideshi Hattori	CU-3633	6288
26530	7590	09/11/2007	EXAMINER	
LADAS & PARRY LLP 224 SOUTH MICHIGAN AVENUE SUITE 1600 CHICAGO, IL 60604				JUNG, UNSU
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/798,001	HATTORI, HIDESHI	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 June 2007.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-25 is/are pending in the application.
  - 4a) Of the above claim(s) 22-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 November 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's reply filed on January 12, 2007 has been acknowledged and entered. The reply included amendments to the specification and claims 14 and 19-21 and addition of new claims 22-25.

***Election/Restrictions***

2. New claims 22-25 in the reply filed on January 12, 2007 have been further restricted in the Restriction dated May 16, 2007. In response to the Restriction, Applicant's withdrawal of new claims 22-25 in the reply filed on June 18, 2007 is acknowledged. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims directed to species (claims 22-25), which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. It is further acknowledged that in the event that no generic linking claim is finally allowed, claims 22-25 may be cancelled from the application.

Claims 13-25 are pending, claims 22-25 have been withdrawn from consideration, and claims 13-21 are under consideration for their merits.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 13-15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaeever (US 3,979,184) in view of McGall et al (US 5,412,087), and in light of Arnold (US 3,982,908).

Giaeever teaches a diagnostic device having a substrate 10 (i.e. substrate), transparent layer 12, second transparent layer 13 (i.e. anti-reflection layer is formed on surface of the substrate), and biological particle layer 14 (i.e. immobilization layer) in succession, wherein the second transparent layer 13 comprises globules having a diameter of 200 Å to 5000 Å (i.e. fine structure comprising fine particle of diameter in the range of 50 nm to 300 nm; depth of from 80 nm to 250 nm). See column 2, lines 51-68; column 3, lines 32-47; column 4, lines 20-24; and Figure 1. In addition, Giaeever teaches that the nature of the second transparent layer is discontinuous (i.e. uneven structure; fine porous structure). See column 2, lines 61-63 and Figure 1. Furthermore,

Giaevers teaches that the biological particle layer can be antigen (i.e. probe biomolecule) and proteins for detecting antibodies. See column 4, line 56 to column 5, line 10.

Giaevers does not explicitly teach that the second transparent layer is porous. However, it is well known in the coating arts that gold with a dimension of about 1 Å to about 1000 Å is naturally porous (see Arnold, column 2, lines 21-23 and lines 32-34). Since Giaevers teaches that the second transparent layer can comprise gold in the form of globules having 200 Å to 5000 Å, one of ordinary skill in the art at the time of the invention would recognize that gold globules of 200Å to 1000A, as taught by Giaevers, would necessarily be porous.

However, Giaevers fails to teach that the immobilization layer is formed in a pattern.

McGall et al teach probes immobilized in an array format, in order to provide discrete locations for distinctive probes, which can then be used to perform a simultaneous, parallel assay to detect different targets. See column 11, lines 13-35. In addition, McGall et al teach that the probes can be proteins and the targets can be antibodies. See column 4, lines 22 and 52-53.

It would have been obvious to one of ordinary skill in the art at the time of the invention to place the probes of Giaevers in an array format, as taught by McGall et al, in order to provide discrete locations for distinctive probes, which can then be used to perform a simultaneous, parallel assay to detect different targets. The benefit of being able to simultaneously detect a plurality of distinct targets through spatial differentiation of distinct probes provides the motivation to combine Giaevers and McGall et al

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references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in replacing the probes of Giaevers with the probe array of McGall et al, since Giaevers teaches protein probes, and the probe array McGall et al can include proteins, thereby allowing the pattern of McGall et al to be deposited upon the globules of Giaevers.

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaevers (US 3,979,184) in view of McGall et al (US 5,412,087) as applied to claims 13-15 above, and further in view of Noblett (US 6,362,004 B1).

Giaevers and McGall et al references have been disclosed above, but fail to teach a mark formed on the substrate for positional detection.

Noblett reference teaches fiducial marks located on predetermined locations with respect to a microarray sample, in order to position and align the sample with greater precision for detection purposes. See abstract and column 3, lines 24-35.

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Giaevers and McGall et al with fiducial marks located on predetermined locations with respect to the probe array, as taught by Noblett, in order to position and align a sample with greater precision for detection purposes. The advantage of more accurate detection, as taught by Noblett, provides the motivation to combine Noblett reference with Giaevers and McGall et al references. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the fiducial marks, as taught by Noblett, in the apparatus of Giaevers and

McGall et al., since Giaevers and McGall et al teach that only a certain part of the substrate comprises immobilized antigen (see Giaevers, column 4, lines 57-60), and the fiducial marks of Noblett provides a means to correctly locate the immobilized antigen.

***Response to Arguments***

**7. Rejection of claims 13-15 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Giaevers in view of McGall et al. and in light of Arnold**

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection.

Applicant's argument that "biological particle layer" is not equivalent to "immobilization layer" but rather equivalent to "probe biomolecule" (p8) is not found persuasive. Giaevers teaches a device comprising a substrate with a monomolecular layer of biological particles, which is interpreted as being the "immobilization layer," which specifically immobilizes select biological particles, which is interpreted as being the "probe biomolecule" (Examples 1 and 2 and column 6, lines 8-10).

Applicant's arguments with respect to claims 22-25 are moot since claims 22-25 have been withdrawn from consideration.

**8. Rejection of claims 16-18 under 35 U.S.C. 103(a) as being unpatentable over Giaevers in view of McGall et al., and further in view of Noblett**

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth in item 7 above.

9. In light of the statements above, Applicant's arguments are not found convincing and the instant claims remained rejected.

***Conclusion***

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/  
Unsu Jung, Ph.D.  
Patent Examiner  
Art Unit 1641

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